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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/521,527	03/08/00	LETURCQ D	ORT1199

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EXAMINER	
VANDER VEGT,F	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 03/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/521,527	Leturcq
Examiner	**Group Art Unit**
F. Pierre VanderVegt	1644

☒ Responsive to communication(s) filed on *Dec 1, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-15* ~~is~~/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *14 and 15* ~~is~~/are allowed.

☒ Claim(s) *1 and 3-13* ~~is~~/are rejected.

☒ Claim(s) *2* is/~~are~~ objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4 & 5*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application claims priority to provisional application 60/124,253.

Applicant should amend the specification at page 1 to reflect the priority information.

Claims 1-15 are currently pending in this application.

Claim Rejections - 35 U.S.C. § 112

1. Claims 4, 8 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

2. The hybridoma cell lines HB-12441 and HB-12657 recited in claims 4 and 8 are essential to the claimed invention. While the production of monoclonal antibodies to a given antigen may be routine, the reproduction of specific monoclonal antibodies is an extremely unpredictable event. The hybridoma cell lines HB-12441 and HB-12657, disclosed on page 5 of the specification, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the hybridomas. It is noted that the deposits have been made under the terms of the Budapest Treaty, however Applicant must provide an affidavit or declaration by Applicant or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridoma cell lines HB-12441 and HB-12657 will be **irrevocably** and without restriction or condition released to the public upon the issuance of a patent in order to satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample **or for the enforceable life of the patent**, whichever is longer. See 37 CFR 1.806.

Amendment of the specification to disclose the date of deposit is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from Applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the Applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

3. Claims 1 and 3-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolating human CD8+ T cells, does not reasonably provide enablement for isolating CD8+ t cells from other species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to the isolation of CD8+ T cells using antibodies which specifically bind to the polypeptide sequence of SEQ ID NO:1. SEQ ID NO:1 is a polypeptide sequence which is present in the alpha chain of human CD8. The sequence appears to be unique to human CD8. Therefore, it is not likely that antibodies specific for SEQ ID NO:1 would be able to bind to CD8+ T cells derived from other animal species. Accordingly, one of skill in the art would not be able to predict with a reasonable expectation of success that a method of isolating CD8+ T cells using antibodies specific for SEQ ID NO:1 would be effective for the isolation, purification or enrichment of CD8+ cells derived from species other than humans. The instant specification does not provide guidance on how to use human specific antibodies to isolate cells from other species.

In view of the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by VanderVegt et al (U on form PTO-892).

The VanderVegt et al reference teaches the use of anti-CD8 monoclonal antibody (mAb) 2.43, which is produced by the hybridoma cell line TIB210 (page 1588, first column in particular). VanderVegt et al teaches that injection of the 2.43 mAb into mice resulted in the depletion of the CD8+ cells, evidencing that the cells were not activated (page 1588, 2nd column in particular). The prior art teaching anticipates the claimed invention.

5. Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,645,837 to Jameson et al (A on form PTO-892).

The '837 patent teaches the sequence for human CD8 alpha chain, comprising or having the amino acid sequence of instant SEQ ID NO:1 within it as residues 59-70 (SEQ ID NO:1 of the '837 patent in particular). Applicant is reminded that the terms "comprising" in claim 11 and "having" in claim 11 are open language terms which allow the inclusion of other amino acid residues up to an including a full-length protein containing the recited sequence. While the '837 patent does not refer to the sequence as "CD8-3," it is respectfully submitted that the term is merely a laboratory designation used by Applicant which does not convey to the artisan any

particular information about the sequence or structure of the referred-to polypeptide. The prior art teaching anticipates the claimed invention.

6. Claim 13 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Whiteside et al (V).

The Whiteside et al reference teaches the isolation of a population of human CD8+ T cells by positive selection (Abstract in particular). While Whiteside et al does not teach Applicant's recited method, Applicant is reminded that claim 13 is a product-by-process claim and that a product remains the same regardless of the process by which it is obtained. The prior art teaching clearly anticipates the claimed invention.

Allowable Subject Matter

7. Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 14 and 15 are allowed.

Conclusion

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

10. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The

Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
March 22, 2001

F. PIERRE VANDERVEGT
PATENT EXAMINER